

Appl. No. 09/889,053  
Docket No. 7379M  
Amdt. dated October 3, 2006  
Reply to Office Action mailed on July 3, 2006  
Customer No. 27752

### REMARKS

#### Claim Status

Claims 1 and 11 have been amended. Claims 3-5 and 7 have been canceled. Claims 12-16 have been added. Claims 1-2 and 8-16 are now pending. Claims 8-10 are withdrawn relating to a non-elected invention. Applicants reserve the right to pursue the original claims in this and other applications. Applicants respectfully request reconsideration of the above-referenced application in light of the amendments and following remarks.

#### 35 U.S.C. § 112, Second Paragraph Rejection

Claims 1 and 11 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The rejection is respectfully traversed. Specifically, claim 1 has been amended to recite "[a] method of determining an amino acid sequence of a polypeptide comprising the steps of: (a) providing the polypeptide, wherein the polypeptide comprises at least one N-terminus; (b) providing a sulfonic acid; (c) adding the sulfonic acid to the polypeptide, wherein said step produces a derivatized analyte; and (d) analyzing said derivatized analyte using a mass spectrometric technique."

The step of using a mass spectrometric technique to determine the amino acid sequence of a polypeptide is well-known. Consequently, this is a step for 'sequencing' a polypeptide. Nonetheless, the addition of 'determining an amino sequence of a polypeptide' has been incorporated for clarification purposes. The claim language "pKa's of less than about 2," and "when coupled" has been omitted from claims 1 and 11.

In addition, claim 11 has been amended to overcome the Examiner's concerns. Specifically, claim 11 recites "[a] method of determining an amino acid sequence of a peptide comprising the steps of: (a) providing the peptide, wherein the peptide comprises at least one N-terminus; (b) providing a sulfonic acid; (c) adding the sulfonic acid to the peptide, wherein said step produces a derivatized analyte; and (d) analyzing said derivatized analyte using a mass spectrometric technique." Consequently, the § 112, second paragraph, rejection of claims 1 and 11 should be withdrawn.

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35 U.S.C. § 102(b) Rejection

Claims 1 and 11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by: Rapid Communication in Mass Spectrometry ("Knierman"), as supported by the Physical Science Information Gateway: Chemical Data Tables. The rejection is respectfully traversed.

The prior art does not disclose the subject matter of amended claims 1 and 11. Specifically, the prior art fails to teach adding sulfonic acid to form a derivatized analyte and analyzing the derivatized analyte. As such, the prior art fails to disclose: "[a] method of determining an amino acid sequence of a polypeptide comprising the steps of: (a) providing the polypeptide, wherein the polypeptide comprises at least one N-terminus; (b) providing a sulfonic acid; (c) adding the sulfonic acid to the polypeptide, wherein said step produces a derivatized analyte; and (d) analyzing said derivatized analyte using a mass spectrometric technique," as recited in claim 1, or "[a] method of determining an amino acid sequence of a peptide comprising the steps of: (a) providing the peptide, wherein the peptide comprises at least one N-terminus; (b) providing a sulfonic acid; (c) adding the sulfonic acid to the peptide, wherein said step produces a derivatized analyte; and (d) analyzing said derivatized analyte using a mass spectrometric technique," as recited in claim 11.

In an anticipation rejection, "[n]o question of obviousness is present. In other words, for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or implicitly. Any feature not directly taught must be inherently present." M.P.E.P. § 706.02. Knierman does not teach the use of sulfonic acid, explicitly or inherently. In fact, Knierman teaches away from using sulfonic acid. Knierman merely teaches digestion of peptides using trifluoroacetic acid and HCl. Knierman does not teach that the addition of sulfonic acid produces a derivatized analyte.

Claims 4 and 5 have been canceled by the present amendment. Consequently, the § 102(b) rejection of claims 1 and 11 is respectfully requested to be withdrawn.

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First 35 U.S.C. § 103(a) Rejection

Claim 1 stands rejected under 35 U.S.C. § 103(a) as being obvious over Knierman, in view of Mass Spectrometry Reviews ("Roth"). The rejection is respectfully traversed.

As indicated above, Knierman does not teach the use of sulfonic acid, explicitly or inherently. Knierman teaches away from using sulfonic acid. Knierman merely teaches digestion of peptides using trifluoroacetic acid and HCl. Knierman does not teach that the addition of sulfonic acid produces a derivatized analyte. Roth is relied upon for disclosing the use of acids or enzymes to digest peptides, generating peptide derivatives and adds nothing to rectify the deficiencies of Knierman. Applicants also respectfully submit that the sulfonic acid is added to produce a derivatized analyte.

As such, the prior art fails to teach or suggest "[a] method of determining an amino acid sequence of a polypeptide comprising the steps of: (a) providing the polypeptide, wherein the polypeptide comprises at least one N-terminus; (b) providing a sulfonic acid; (c) adding the sulfonic acid to the polypeptide, wherein said step produces a derivatized analyte; and (d) analyzing said derivatized analyte using a mass spectrometric technique," as recited in claim 1.

Second 35 U.S.C. § 103(a) Rejection

Claim 1 stands rejected under 35 U.S.C. § 103(a) as being obvious over Knierman, in view of Analytic Biochemistry ("Stolowitz"). The rejection is respectfully traversed.

As indicated above, Knierman does not teach the use of sulfonic acid, explicitly or inherently. Knierman teaches away from using sulfonic acid. Knierman merely teaches digestion of peptides using trifluoroacetic acid and HCl. Knierman does not teach that the addition of sulfonic acid produces a derivatized analyte. Stolowitz is relied upon for disclosing mass spectral analysis of derivatives, and adds nothing to rectify the deficiencies of Knierman.

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Applicants also respectfully submit that there is *no* motivation to combine Knierman and Stolowitz. Knierman discloses the use of trifluoroacetic acid and HCl, and Stolowitz discloses the use of sulfonic acid *chlorides*.

As such, even if the references are properly combinable, which they are not, they still would fail to teach or suggest "[a] method of determining an amino acid sequence of a polypeptide comprising the steps of: (a) providing the polypeptide, wherein the polypeptide comprises at least one N-terminus; (b) *providing a sulfonic acid*; (c) adding the sulfonic acid to the polypeptide, wherein said step produces a derivatized analyte; and (d) analyzing said derivatized analyte using a mass spectrometric technique," as recited in claim 1 (emphasis added). The combination would use trifluoroacetic acid, HCl and a sulfonic acid *chloride*.

Judicially-Created Doctrine of Obviousness-type Double-Patenting Rejection

Claims 1-2 and 5 stand provisionally rejected under the judicially-created doctrine of obviousness-type double-patenting as being unpatentable over claims 1-3, 5, and 10 of co-pending Application No. 09/863,786 (the '786 application). The provisional rejection is respectfully traversed.

At the outset, Applicants note that the Office Action asserts that the April 12, 2006 amendment did not respond to this rejection. Applicants respectfully disagree. Nonetheless, Applicants have amended claim 1 to overcome the Examiner's objection.

Claim 1 now recites "[a] method of determining an amino acid sequence of a polypeptide comprising the steps of: (a) providing the polypeptide, wherein the polypeptide comprises at least one N-terminus; (b) *providing a sulfonic acid*; (c) *adding the sulfonic acid to the polypeptide*, wherein said step produces a derivatized analyte; and (d) *analyzing said derivatized analyte using a mass spectrometric technique*," (emphasis added). As such, the double-patenting rejection should be withdrawn.

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Conclusion

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied references. All matters raised by the Office Action are believed to be addressed by the remarks made hereunder. The claims have been amended in accordance with the law.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to review and pass this application to issue. In view of the foregoing, Applicants respectfully request reconsideration of this application, entry of the amendments presented herein, and allowance of the pending claims.

Respectfully submitted,

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